

**REMARKS**

Claims 1-21 have been canceled.

Claims 22-31 are pending.

No new matter has been entered.

**Rejections Under 35 USC § 102**

The Examiner has rejected claims 22-23 and 28-29 as anticipated by Demmer et al. (US 6,001,974). The Examiner states that his rejection is based on Demmer's anticipation of steps (2) and (3) as described in instant claim 22. Specifically, the Examiner contends that Demmer et al. disclose a method of preparing a product solution by removing biological components from a human derived biological components-containing solution by subjecting the biological solution to the following two treatment steps in succession. The first step is removing a portion or all of proteins having a molecular weight to or higher than that of albumin by fractionation with a molecular sieve and retaining a portion of the solution from which the proteins have been removed (treatment performed in module 1); the Examiner contends that this step is equivalent to step (2) of claim 22. The second step is concentrating proteins by passing a solution through a porous separation membrane wherein the product solution is retained and treated portion of the solution from at least two of the three treatment steps (treatment performed in module 2); this equates to step (3) of claim 22. Applicants respectfully traverse.

Further to the arguments made in the Response filed April 28, 2010, Applicants submit a Declaration from Dr. Kazuhiro Tanahashi in support of the novelty of the claimed invention. This Declaration states that Demmer et al. uses ion exchange in both module 1 and module 2 of the Demmer et al. invention and that Demmer et al. do not use a molecular sieve as required by step (2) of the instant invention.

In view of the above, Applicants respectfully request removal of the rejection.

Rejections Under 35 USC § 103*Demmer et al. in view of Kim et al.*

The Examiner has rejected claims 24-26 and 30 as obvious over Demmer et al. in view of Kim et al. (US 7,441,666). The Examiner states that the rejection is based on the selection of steps (2) and (3) of the instant claims. The Examiner's allegations concerning the Demmer et al. reference are set forth above. Regarding Kim et al., the Examiner contends that Kim et al. uses a molecular sieve (equating to step 2 of the instant claims) and a porous separation membrane selected from cellulose and a polyamide. The Examiner concludes that it would have been obvious to use a molecular sieve and/or separation membrane as disclosed by Kim et al. in the method of Demmer et al. Applicants respectfully traverse.

The Declaration by Dr. Kazuhiro Tanahashi submitted with this Supplemental Response also addresses the Examiner's obviousness rejection. Dr. Tanahashi states that while Kim et al. remove albumin by employing fractionation with a molecular sieve, the skilled artisan would not have a reasonable expectation of success in simply substituting the molecular sieve used by Kim in the Demmer et al. method. A significant difference in pore size between the ion exchange filter used by Demmer et al. and the molecular sieve used by Kim et al. would prevent the separation which occurs in the anionic exchange portion of the Demmer et al. procedure which removes many of the "contaminants." Further, use of the Kim et al. membrane would not allow for cationic exchange in the Demmer et al. procedure.

Consequently, in view of the above, Applicants request removal of the rejections.

*Demmer et al. in view of Comper*

The Examiner rejects claim 27 as obvious over Demmer et al. in view of Comper. The Examiner's allegations regarding the Demmer et al. reference are set forth above. With respect to Comper, the Examiner states that Comper discloses the use of a blue dye in order to detect albumin in a solution during a filtration process. The Examiner concludes that it would have

been obvious to the skilled artisan to add Comper's blue dye to the Demmer et al. procedure to detect the amount. Applicants respectfully traverse.

The Dr. Kazuhiro Tanahashi Declaration states that many times addition of dyes, such as that used by Comper, alter the net charge associated with protein molecules, which change the dynamics of an ion exchange system and therefore cannot be counted upon to produce the same effect. Thus, Applicants request removal of the rejection.

### Conclusion

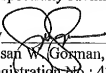
In view of the above remarks, all of the claims are submitted as defining non-obvious, patentable subject matter. Reconsideration of the rejections and allowance of the claims are respectfully requested.

If any questions arise in the above matters, please contact Applicant's representative, Susan W. Gorman (Reg. No. 47,604), in San Diego, California at the phone number listed below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By   
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Enclosures: Dr. Kazuhiro Tanahashi Declaration